UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,846	04/20/2004	Steven R. Binder	02558B-063710US	5304

20350 7590 10/11/2007

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,846	BINDER ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks, 07/27/2007, have been fully considered. The following rejections and/or objections are maintained, newly applied, or withdrawn for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

STATUS OF THE CLAIMS

Claims 1-31 are herein under examination, as they read on the species of systemic autoimmune disease (SLE) and antigens (Scl-70). Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1-5 and 11-31 remain rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Thompson et al. (Lupus, 1993, 2, p.15-19) and Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765), and further supported by Anderson et al. (WO/1999/039298; Filed 03/02/1999).

Applicant arguments that (i) none of the above references teaches reference data sets for "disease-free patients" and (ii) none of the above references teaches "storing a plurality of reference data sets...wherein said reference data sets include at least one reference data set

associated with none of the specific SADs" or a "memory module that stores a plurality of reference data sets..., wherein said reference data sets include at least one reference data set associated with none of the specific SADs" have been fully considered but are not persuasive for the following reasons.

In response to (i): applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies ("disease free patients") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to (ii): Zimmerman teaches a procedure for comparison of autoantibody blots (i.e. data sets) comprising the statistical comparison of any group of staining patterns, e.g. those derived from patients with autoimmune diseases or normal controls, the identification of the bands that contribute most to the differences between such groups, and the determination whether an unknown individual sample belongs to a known group [Abstract]. Furthermore, their multivariate approach for classifying unknown samples is based on a continuum of "normal" and "diseased" sample sera, wherein each is described by variables representing a particular staining behavior [p.946, Section 4]. Zimmerman also describes the software [Section 2.2] and hardware [Section 2.3] for implementing the above method, which inherently includes memory for storing data. Therefore, the Examiner maintains that Zimmerman teaches normal controls or reference data sets (i.e. not of the one or more autoimmune diseases), as well as memory "modules" and means for storing data.

Thompson was relied upon as a teaching for patients with systemic lupus erythmatosus (SLE) based on their autoantibody profile (Abstract). Applicants have not argued this point.

Kim was relied upon as a teaching for a fast k-nearest neighbor (kNN) search algorithm based on ordered partitions (Abstract). Applicants have not argued this point.

For the above reasons, and for those set forth in detail in the office action mailed 02/07/2007, the Examiner maintains that it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Zimmerman et al. using the SLE antibody profiles of Thompson et al., and the added feature of a "k-nearest neighbor" algorithm taught by Kim et al., where the motivation would have been to improve automated diagnosis of SLE with a more robust statistical "kNN" procedure [Zimmerman et al., Section 4]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Anderson et al., who teach a decision-support computer system using neural network algorithms to classify and identify patterns in antibody data for disease diagnosis [WO/1999/039298; Filed 03/02/1999, Summary of the Invention].

Claims 6-10 and 22-24 remain rejected under 35 U.S.C. 103(a) as being obvious by Thompson et al. (Lupus, 1993, 2, p.15-19), in view of Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765) and Diamond et al. as applied to claims 1-5 and 11-14, above, and further in view of Kopecky (Design and Implementation of the Internet-Based Medical Expert System ToxoNet, 1999, p.1-153)

Applicant arguments that (i) none of the above references teaches reference data sets for "disease-free patients" and (ii) none of the above references teaches "storing a plurality of reference data sets...wherein said reference data sets include at least one reference data set associated with none of the specific SADs" or a "memory module that stores a plurality of

reference data sets..., wherein said reference data sets include at least one reference data set associated with none of the specific SADs" have been fully considered but are not persuasive for the following reasons.

In response to (i): Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies ("disease free patients") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to (ii): Thompson teaches a distribution of autoantibody profiles in 117 SLE patients [Table I, below]. Profile data sets are provided that are not associated with any of the SADs required by the claims. For example, the claims do not recite "Drug-induced lupus" or "Incomplete lupus." Furthermore, Tables III and IV provide "negative" profiles indicative of datasets not associated with disease. Therefore, the Examiner maintains that the teachings of Thompson have been broadly and reasonably interpreted as a teaching for reference data sets that include at least one reference data set associated with none of the specific SADs.

Kopecky teaches an internet-based medical expert system (ToxoNet) for providing automated decision support to the clinician. ToxoNet consists of three parts: ToxoServer, ToxoBuilder, and ToxoApplet [Results Section]. ToxoServer stores and retrieves patient data from the database [Section 3.2.2]. Data is transmitted across a network to ToxoApplet [Fig. 3.3], which correlates to instant claims 8. The computer system comprises input/output devices and memory [p.60], as well as a monitor and printer [p.123], as in instant claims 22-24. Therefore, it would have been a matter of common sense for one of ordinary skill in the art to practice the method of Thompson using an automated system for storing and processing data.

For the above reasons, and for those set forth in detail in the office action mailed 02/07/2007, the Examiner maintains that it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the antibody profiles of Thompson et al. with the k-nearest neighbor searching algorithm of Kim et al. and the internet-based decision support system of Kopecky, where the motivation would have been to integrate autoimmune disease databases with a World Wide Web interface to provide remote automated decision support (Kopecky [1.1]), resulting in the practice of the instant claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Diamond et al., who teach an automated decision support system combining computer-implemented methods and analysis of immunological data sets [Abstract].

Provisional Obviousness-Type Double Patenting Rejection

Applicant has not set forth any arguments regarding this rejection. This rejection is therefore maintained and reiterated.

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, and 17 of co-pending Application No. 09/691,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of '405 recite the same method steps, with minor variations. For example, claims 1-3 of the instant application and claims 1-3 of co-pending Application '405 are directed to computer-implemented methods for identifying specific autoimmune diseases using a 'k-nearest neighbor' algorithm. It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the appropriate plurality of antibodies and then compare test data and stored reference data using said algorithm to identify disease. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

No claims are allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley
Patent Examiner
Art Unit 1631
Office: 571-272-4425
Direct Fax: 571-273-4425

MICHAEL BORIN, PH.D
PRIMARY EXAMINER